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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,572

04/21/2004

Steven A. McAuley

1001.1704101

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06/08/2006

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MINNEAPOLIS, MN 55403-2420

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,572	<b>Applicant(s)</b> MCAULEY ET AL.	
	<b>Examiner</b> Laura A. Bouchelle	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 January 1935.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-20 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-20 and 22-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/25/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 7, 9, 11, 12, 14, 20, 26, 27, 29, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig (US 6264633) in view of Termin et al (US 5221261)). Knorig discloses the limitations of dependent claims 7, 9, 14, 20, 26 and 27. Knorig discloses a balloon catheter comprising a catheter 10, a balloon 11, a guidewire lumen 18, and an inflation lumen 25, wherein the balloon has undulations that serve as gripping surfaces 12 to cling to the surfaces adjacent to the balloon. See Fig. 1.

3. Claims 1, 13, 25, 29, 35 differ from Knorig in calling for the catheter to have a traction member with a free proximal end. Claim 11 calls for the traction member to be coupled at the first end. Claim 12 calls for the first end of the member to be coupled to the balloon. Termin teaches a balloon catheter with a traction member 22 coupled to the shaft and the balloon at the first end and having a free proximal end so that the traction member is free to move axially relative to the catheter as the balloon expands (Col. 4, line 60 – Col. 5, line 5). Therefore, it

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would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Knorig to have a traction member with a free proximal end as taught by Termin to allow the traction member is free to move axially relative to the catheter as the balloon expands.

4. Claims 2 and 15, and 6 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Termin et al as applied to claims 1 and 13 above, and further in view of Mareiro et al (US 6258099). Claims 2 and 15 differ from the above teachings in calling for the gripping surface to be bumps. Claims 6 and 19 call for the gripping surface to be spikes. Mareiro discloses a balloon catheter having a gripping surface comprising bumps (Fig. 5e) or spikes (Fig. 5c) to increase the retention characteristics of the balloon (Col. 4, lines 56-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the balloon catheter of Knorig in view of Termin to include gripping surfaces that are either bumps or spikes as taught by Mareiro to increase the retention characteristics of the balloon within the conduit.

5. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Termin et al as applied to claims 1 and 13 above, and further in view of Bradshaw (US 6450988). Claims 3 and 16 differ from the above teachings in calling for the gripping surface to be defined by a helical region. Bradshaw discloses a balloon catheter, wherein the balloon comprises a region of helical lobes 26 with protruding knobs 30 that engage the vessel wall while allowing for a perfusion channel (Col. 4, lines 40-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the gripping member

of Knorig in view of Termin to be of a helical shape as taught by Bradshaw so that the balloon engages the wall of the vessel while allowing for perfusion through the channel.

6. Claims 4 and 17, and 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Termin et al as applied to claims 1 and 13 above, and further in view of Grayzel et al (US 2002/0010489). Claims 4 and 17 differ from the above teachings in calling for the gripping surface to be defined by a ridge along the body portion. Claims 5 and 18 call for the gripping surfaces to be defined by saw tooth projections. Grayzel discloses a balloon catheter comprising gripping member in the shape of a ridge 46 or alternatively in the shape of saw tooth projections 500. See Figs. 2 and 9G. These configurations facilitate the dilation of the target lumen by the expanding balloon (Page 4, paragraph 0053). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the gripping surfaces of Knorig in view of Termin to be either a ridge or saw tooth projections as taught by Grayzel to facilitate the dilation of the target lumen by the expanding balloon.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Termin et al as applied to claim 9 above, and further in view of Campbell (US 5928193). Claim 10 differs from the teachings above in calling for the guidewire to extend distally out the end of the guide lumen. Campbell discloses a balloon catheter wherein the guidewire 82 extends through the lumen and past the balloon for rapid exchange of the guidewire (Col. 5, lines 1-4). See Figs. 7 and 8. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the balloon catheter of Knorig in view of Termin such that the

guidewire extends past the distal end of the guide lumen as taught by Campbell to allow for rapid exchange of the catheter.

8. Claims 22- 24, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Termin et al. Claims 22- 24, and 29-32 differ from the teachings above in calling for the proximal end of the traction member to be disposed at either the proximal waist, the midpoint, or the distal waist of the balloon. At the time the invention was made, it would have been an obvious matter of design choice to have the proximal end of the traction member disposed at any of the above stated locations. Applicant has not disclosed that having the proximal end of the traction member disposed in a specific location serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect the device of Knorig in view of Hart to perform equally well with the proximal end of the traction member disposed at any of the stated locations. Therefore, it would have been prima facie obvious to modify Knorig in view of Termin to obtain the invention as specified in claims 22-24, and 30-32 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Knorig in view of Termin.

9. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knorig in view of Amundson et al (US 5484449). Claims 33 and 34 differ from Knorig in calling for a non-woven traction member. Knorig teaches a balloon catheter having a non-woven wire traction member 50 to maintain contact with the body lumen (Col. 6, lines 20-60). Therefore, it

would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Knorig to have a non-woven traction member as taught by Amundson to maintain contact with the body lumen.

***Response to Arguments***

10. Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura A Bouchelle  
Examiner  
Art Unit 3763

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